



0769 5 NOV -7 P1:58

SEP 22 2005

Mr. Jim Starr
Director, Product Development
Apex Fitness Group
100 Camino Ruiz
Camarillo, California 93012

Dear Mr. Starr:

This is in response to your letter of July 29, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Apex Fitness Group is making the claim "[T]his formula may reduce the risk of osteoporosis...." The product contains magnesium and vitamin D.

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in these regulations may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis. Your product does not appear to meet the eligibility requirements to bear the authorized health claim for calcium and osteoporosis because it does not contain calcium. As such, because it bears a disease claim, your product appears to be a drug under 21 U.S.C. 321(g)(1)(B).

We would also like to note one other issue with your notices. 21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification


97S 0163 LET 847

Page 2 - Mr. Jim Starr

requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJ Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Compliance, HFR-PA240



Apex Fitness Group™
100 Camino Ruiz
Camarillo, CA 93012

GEN	TEL	FAX
800	805	805
656	449	449
2739	1330	1370

apexfitness.com

July 29, 2005

AUG - 9

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403 (r)(6)(21 U.S.C. 343(r)(6)) of the Federal Food Drug and Cosmetic Act that Apex Fitness Group, 100 Camino Ruiz, Camarillo, CA 93012 has marketed a dietary supplement under Apex Fitness Group Fit Advanced "Calcium " bearing the following statement(s) on the label and/or in the labeling:

(Statement 1) Maintain bone health (with vitamin D & magnesium)

(Statement 2) "This formula contains calcium and magnesium, which are used by the body to maintain bone and normal muscle and nerve activity. The magnesium contained in this product also assists in better calcium homeostasis. This product's Advanced Delivery System is designed to provide more effective mineral absorption. In addition to regular exercise and a healthy diet, this formula may reduce the risk of osteoporosis, which is prevalent in Asian and Caucasian postmenopausal women".

The undersigned certifies that the information contained in this notice is complete and accurate and that Apex Fitness Group has substantiation that the statement(s) is truthful and not misleading. Pursuant to 101.93 (a)(1), two copies of this notification are enclosed.

Jim Starr
Director Product Development

Aims
2005-6051

9/2/05

#1361